

## **ENERGY BASED DEVICES AND METHODS FOR TREATMENT OF PATENT FORAMEN OVALE**

### **CROSS-REFERENCES TO RELATED APPLICATIONS**

- 5 [0001] This application claims priority to U.S. Provisional Patent Application Nos. 60/458,854 (Attorney Docket No. 20979-002100US), filed on March 27, 2003; 60/478,035 (Attorney Docket No. 20979-002110US), filed on June 11, 2003, and 60/490082 (Attorney Docket No. 20979-002120US), filed on July 24, 2003, the full disclosures of which are incorporated herein by reference. This application is related to U.S. Patent Application Nos.
- 10 10/665974 (Attorney Docket No. 20979-002600US), filed on September 18, 2003, and 10/679245 (Attorney Docket No. 20979-002500US), filed on October 2, 2003, <sup>now US Patent No. 6,937,348</sup> the full disclosures of which are incorporated herein by reference.

### **BACKGROUND OF THE INVENTION**

- [0002] The invention generally relates to medical devices and methods. More specifically,
- 15 the invention relates to energy based devices, systems and methods for treatment of patent foramen ovale.

- [0003] Fetal blood circulation is much different than adult circulation. Because fetal blood is oxygenated by the placenta, rather than the fetal lungs, blood is generally shunted away from the lungs to the peripheral tissues through a number of vessels and foramens that remain
- 20 patent (i.e., open) during fetal life and typically close shortly after birth. For example, fetal blood passes directly from the right atrium through the foramen ovale into the left atrium, and a portion of blood circulating through the pulmonary artery trunk passes through the ductus arteriosus to the aorta. This fetal circulation is shown in attached Figure 1.

- [0004] At birth, as a newborn begins breathing, blood pressure in the left atrium rises above
- 25 the pressure in the right atrium. In most newborns, a flap of tissue closes the foramen ovale and heals together. In approximately 20,000 babies born each year in the US, the flap of tissue is missing, and the hole remains open as an atrial septal defect (ASD). In a much more significant percentage of the population (estimates range from 5% to 20% of the entire population), the flap is present but does not heal together. This condition is known as a
- 30 patent foramen ovale (PFO). Whenever the pressure in the right atrium rises above that in the